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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,632	06/09/2000	Susan Lindquist	27373/34978A	2820

7590 05/24/2007
Marshall O'Toole Gerstein
Murray & Borun
6300 Sears Tower
233 South Wacker Drive
Chicago, IL 60606-6402

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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05/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/591,632	Applicant(s) LINDQUIST ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67,81,101,103-110,117,118,121-135,137-140 and 143-162 is/are pending in the application.

4a) Of the above claim(s) 67,81,101,103-110,117,118,143,146-149,156 and 162 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 121-123,130,132,133,139,140,144,145,150-155 and 157-161 is/are rejected.
- 7) ☒ Claim(s) 124-129,131,134,135,137 and 138 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: copy of sequence alignment, two pages.

DETAILED ACTION

Response to Amendment

1. Claims 124, 126, 130-133, 140 and 150 have been amended and claim 65 has been cancelled as requested in the amendment filed on December 27, 2006. Following the amendment, claims 67, 81, 101, 103-110, 117, 118, 121-135, 137-140, 143-162 are pending in the instant application.
2. Claims 67, 81, 101, 103-110, 117, 118, 143, 146-149, 156 and 162 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Papers filed on May 13, 2002 and May 09, 2005.
3. Claims 121-135, 137-140, 144, 145, 150-155 and 157-161 are under examination in the instant office action.
4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
5. Applicant's arguments filed on December 27, 2006 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 121-123, 139-140, 144-145, 150-155 and 157-161 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for those reasons of record as set forth in section 11 of Paper mailed on June 26, 2006. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Briefly, claims 121-123, 139-140, 144-145, 150-155 and 157-161 encompass fragments of a polypeptide of SEQ ID NO: 2, fragments of the fragments of the polypeptide of SEQ ID NO: 2, fragments of the polypeptides with a limited structural similarity to the polypeptide of SEQ ID NO: 2, and molecular embodiments, which are sequence variants of the above recited fragments (defined as having insertions, additions, deletions and substitutions within the variant sequence, see claim 150, for example), wherein the claimed fragments have the ability to self-coalesce into ordered aggregates. The claims do not require that the recites fragments possess any particular conserved structure or other disclosed distinguishing feature, which supports the ability of the fragments to form ordered aggregates. The instant specification fails to describe the genus of the claimed fragments, and, as such, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore the claims, which encompass the various fragments of the polypeptide of SEQ ID NO: 2 do not meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant traverses the instant rejection at pp. 13-22 of the Response. The Examiner agrees that “[i]t is not necessary to provide an exhaustive list of fragments and variants of SEQ ID NO: 2 in order to comply with written description requirement” (p. 15). However, since the

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instant specification did not describe the structure within the polypeptide of SEQ ID NO: 2, which is critical for formation of ordered aggregates, or disclosed a sufficient number of representative fragments and variants that meet the structural limitations of the claims and self-coalesce into ordered aggregates, one skilled in the art undoubtedly could not “clearly envision each sequence based on the language of the claims and the knowledge of one of skill in the art” (p. 15 of the Response). Further, by stating that, “fragments and variants that self-coalesce into ordered aggregates can be easily distinguished from those that do not” (p. 15), Applicant appears to be taken the position that 35 U.S.C. 112, first paragraph, permits an artisan to present claims of essentially limitless breadth as long as the specification provides one with the ability to test any particular embodiment, which is encompassed by the material limitations of a claim and thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don’t. However, this “make and test” approach does not satisfy the written description requirement of 35 U.S.C. 112, first paragraph, which requires that the specification must provide sufficient distinguishing identifying characteristics of the claimed genus in the form of disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the absence of sufficient recitation of distinguishing identifying characteristics of the claimed molecules, such as in the instant case those fragments of a polypeptide of SEQ ID NO: 2, fragments of the fragments of the polypeptide of SEQ ID NO: 2, fragments of the polypeptides with a limited structural similarity to the polypeptide of SEQ ID NO: 2, and molecular embodiments, which are sequence variants of the above recited fragments, wherein the claimed fragments have the ability to self-coalesce into ordered aggregates, the

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specification does not provide adequate written description of the claimed genus. Thus, the instant rejection is maintained.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 121-122, 139 and 144 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kushnirov et al, Yeast, 1990, 6, pp. 461-72.

Applicant traverses the rejection on the premises that “Applicants are not claiming every polypeptide that self-coalesces and that comprises any fragment of SEQ ID NO: 2. Claim 144 specifies that the fragment itself self-coalesces to form higher ordered aggregation” (p. 28 of the Response). Applicant’s argument has been fully considered but it is unpersuasive because the claims, as written, encompass fragments of SEQ ID NO: 2 and the instant specification fails to describe the specific structure of those fragments that self-coalesce to form aggregate from “any fragment of SEQ ID NO: 2” (see reasoning in section 7 of the instant office action). As such, by broadest reasonable interpretation, document of Kushnirov et al. fully discloses the fragments recited in claims 121-122, 139 and 144.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 139-140, 144-145, 150-155 and 157-161 stand rejected under 35 U.S.C. 102(e) as being anticipated by Prusiner et al, US Patent 6,277,970 for reasons of record in section 18 of Paper mailed on June 26, 2006.

Applicant traverses the rejection on the premises that "Applicants are not claiming every polypeptide that self-coalesces and that comprises *any* fragment of SEQ ID NO: 2" (p. 29 of the Response). Applicant's arguments have been fully considered but it is unpersuasive because the claims, as written, encompass fragments of SEQ ID NO: 2 and the instant specification fails to describe the specific structure of those fragments that self-coalesce to form aggregate from "*any* fragment of SEQ ID NO: 2" (see reasoning in section of the instant office action). As such, by broadest reasonable interpretation, patent of Pruisner et al. fully discloses the fragments recited in claims 139-140, 144-145, 150-155 and 157-161.

New grounds of rejection necessitated by amendment

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 130 and 132-133, as currently amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claim 130 is vague and indefinite for recitation "appear substantially the same". This recitation relates to appearance of the aggregates, which is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of appearance being "substantially the same", and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

16. Claims 132-133 are vague and indefinite for recitation "except at position 2". The metes and bounds of the recitation cannot be determined from the claims or the instant specification, as filed. Clarification is required.

Claim Objections

17. Claims 124-129, 131, 134, 135, 137 and 138 are objected to for the following reasons. Claims 124-129, 131, 134, 135, 137 and 138 encompass polypeptide of SEQ ID NO: 2 with amino acid residues substituted at the specific positions within the SEQ ID NO: 2. Applicant is advised that substitution of one amino acid residue within a polypeptide sequence by definition produces a different polypeptide, which is no longer defined by SEQ ID NO: 2. Considering that (1) a polypeptide of SEQ ID NO: 2 is known in prior art from 1987 as Sup35 protein (see Kushnirov et al. 1988, Gene, 66, pp. 45-54, and sequence alignment attached to the instant office action), and that (2) the currently claimed protein is no longer defined by SEQ ID NO: 2, it is

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impossible to run a meaningful sequence search of the relevant databases or even more impossible to compare sequences manually. In order to determine if the instant invention was known in the prior art, Applicant is advised to assign a proper SEQ ID NO: for the molecular embodiments claimed.

Conclusion

18. Claims 124-129, 131, 134, 135, 137 and 138 are objected to. Claims 121-123, 130, 132, 133, 139-140, 144, 145, 150-155 and 157-161 are rejected.

19. This application contains claims 67, 81, 101, 103-110, 117, 118, 143, 146-149, 156 and 162 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

May 21, 2007

<!--StartFragment-->RESULT 1

EFBYS2

suppressor 2 protein - yeast (*Saccharomyces cerevisiae*)

N;Alternate names: G1-to-S transition protein; protein YD9395.05; protein YDR172w

C;Species: *Saccharomyces cerevisiae*

C;Date: 31-Dec-1991 #sequence_revision 31-Dec-1991 #text_change 09-Jul-2004

C;Accession: S00733; JT0323; S49768; S00488; A26742; S00533; S05723

R;Wilson, P.G.; Culbertson, M.R.

J. Mol. Biol. 199, 559-573, 1988

A;Title: SUF12 suppressor protein of yeast. A fusion protein related to the EF-1 family of elongation facto

A;Reference number: S00733; MUID:88172503; PMID:3280807

A;Accession: S00733

A;Molecule type: DNA

A;Residues: 1-685 <WIL>

A;Cross-references: UNIPROT:P05453; EMBL:X07163; NID:g4581; PIDN:CAA30155.1; PID:g4582

R;Kushnirov, V.V.; Ter-Avanesyan, M.D.; Telckov, M.V.; Surguchov, A.P.; Smirnov, V.N.; Inge-Vechtomov, S.G.

Gene 66, 45-54, 1988A;Title: Nucleotide sequence of the SUP2(SUP35) gene of *Saccharomyces cerevisiae*.

A;Reference number: JT0323; MUID:88329727; PMID:3047009

A;Accession: JT0323

A;Molecule type: DNA

A;Residues: 1-685 <KUS>

A;Cross-references: EMBL:M21129; NID:g172789; PIDN:AAA35133.1; PID:g172791

R;Murphy, L.; Harris, D.E.

submitted to the EMBL Data Library, November 1994

A;Reference number: S49764

A;Accession: S49768

A;Molecule type: DNA

A;Residues: 1-685 <MUR>

A;Cross-references: EMBL:Z46727; NID:g1289283; PIDN:CAA86677.1; PID:g1289287; GSPDB:GN00004; MIPS:YDR172w

R;Kikuchi, Y.; Shimatake, H.; Kikuchi, A.

EMBO J. 7, 1175-1182, 1988

A;Title: A yeast gene required for the G1-to-S transition encodes a protein containing an A-kinase target s

A;Reference number: S00488; MUID:88296422; PMID:2841115

A;Accession: S00488

A;Molecule type: DNA

A;Residues: 1-52, 'C', 54-685 <KIK>

A;Cross-references: GB:Y00829; EMBL:Y00859; NID:g3711; PIDN:CAA68760.1; PID:g3712

C;Genetics:

A;Gene: SGD:SUP35; SUF12; GST1; SUP2; MIPS:YDR172w

A;Cross-references: SGD:S0002579; MIPS:YDR172w

A;Map position: 4R

C;Superfamily: suppressor 2 protein; translation elongation factor Tu homology

C;Keywords: duplication; GTP binding; nucleotide binding; P-loop; phosphoprotein; tandem repeat

F;1-123/Domain: A <DOM1>

F;42-119/Region: 10-residue repeats

F;124-253/Domain: charged <DOM2>

F;159-222/Region: glutamic acid/lysine-rich

F;254-685/Domain: C <DOM4>

F;261-409/Domain: translation elongation factor Tu homology <ETU>

F;267-274/Region: nucleotide-binding motif A (P-loop)

F;406-409/Region: GTP-binding NKXD motif

F;273/Binding site: GTP (Lys) #status predicted

Query Match 100.0%; Score 3594; DB 1; Length 685;

Best Local Similarity 100.0%; Pred. No. 1.1e-178;

Matches 685; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy    181  EPTKEPTKVEEPVKKEEKPVTKEEKEKSELPKVEDLKISESTHNTNNAVTSADALIK 240
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Db    181  EPTKEPTKVEEPVKKEEKPVTKEEKEKSELPKVEDLKISESTHNTNNAVTSADALIK 240

Qy    241  EQEEEVDDVEVNDMFGGKDHVSLIFMGHVDAGKSTMGGNLLYLTGSDVKRTIEKYEREA 300
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Qy      361 QADVGVLVISARKGEYETGFERGGQTRHALLAKTQGVNKMVVVNKMDPTVNWSKERY 420
      |||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      361 QADVGVLVISARKGEYETGFERGGQTRHALLAKTQGVNKMVVVNKMDPTVNWSKERY 420
Qy      421 DQCVSNVSNFLRAIGYNIKT DVVFMPVSGYSGANLKD HVDPK ECPWYTGPTLLEYLDTMN 480
      |||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      421 DQCVSNVSNFLRAIGYNIKT DVVFMPVSGYSGANLKD HVDPK ECPWYTGPTLLEYLDTMN 480
Qy      481 HVDRHINAPFMLPIAAKMKDLGTIVEGKIESGHIKKGSTLLMPNKTAVEIQNIYNETEN 540
      |||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      481 HVDRHINAPFMLPIAAKMKDLGTIVEGKIESGHIKKGSTLLMPNKTAVEIQNIYNETEN 540
Qy      541 EVDMA MCGEQVKLR IKGVEEEDISP GFVLTSPKNPIKSVTKFVAQIAIVELKSIIAAGFS 600
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Qy      601 CVMHVHTAIEEVHIVKLLHKLEKGTNRKSKKP PAF AKKG MKVIAVLETEAPVCVETYQDY 660
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Db      601 CVMHVHTAIEEVHIVKLLHKLEKGTNRKSKKP PAF AKKG MKVIAVLETEAPVCVETYQDY 660
Qy      661 PQLGRFTLRDQGT TIAIGKIVKIAE 685
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<!--EndFragment-->